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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------------|------------------------|
| 10/811,661 | 03/29/2004 | Christian Woll | 23861/3 | 2443 |
| 7590 Joseph P. Quinn, Esq. Brown Rudnick Berlack Israels LLP One Financial Center Box IP Boston, MA 02111 | | 05/15/2007 | EXAMINER PRIDDY, MICHAEL B | |
| | | | ART UNIT 3733 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/811,661 | WOLL ET AL. |
| | Examiner | Art Unit |
| | Michael B. Priddy | 3733 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 26 April 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-32 is/are pending in the application.
 - 4a) Of the above claim(s) 24-32 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-12 and 16-23 is/are rejected.
- 7) Claim(s) 13-15 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 20041105 & 20050705.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of invention I in the reply filed on 04/26/2007 is acknowledged. The traversal is on the ground(s) that searching both of the inventions set forth in the restriction requirement of 04/04/2007 would not be burdensome to the Examiner. This is not found persuasive because contrary to Applicant's opinion, searching both inventions simultaneously is burdensome to the Examiner because every distinct invention requires a different search strategy regardless of the subclasses actually searched.

The requirement is still deemed proper and is therefore made FINAL.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 2-6 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In line 5 of claim 2 and lines 12-13 of claim 23, Applicant has recited "wherein said at least partially transverse proximal surface... serves as said distal stop." Because Applicant has already recited the "distal stop" in line 3 of claim 1 and line 3 of claim 23 respectively, it is unclear whether the partially transverse proximal surface and the distal stop are the same structural element or two different structural elements. This causes the scope of the claims to be unclear.

Furthermore, in line 14 of claim 23, Applicant has recited "wherein said guide wire includes a distal stop having a width greater than the diameter of said longitudinal through hole" while "a distal stop" has already been required to be "disposed on said guide wire about adjacent to said guide wire distal end" in line 3. It is unclear whether Applicant intends to encompass a second distal stop in line 14 or merely modify the previously recited distal stop of line 3.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1, 7-9, 11, 12, 16-18, 20 & 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Davies (GB 2,268,068). Davies teaches a guide wire 2 having a proximal end and a distal end; a distal stop 14 disposed on said guide wire 2 about adjacent to said guide wire distal end; a proximal stop 18/20 disposed on said guide wire 2 about adjacent to said guide wire proximal end; and a flexible tube 4 disposable over said guide wire 2 and having a sidewall including a radially expandable anchor portion 4a adapted for radial expansion upon compression of said tube 4 between said distal stop 14 and said proximal stop 18/20; wherein said proximal stop is formed as a distal surface of a compression fastener comprises at least one nut threaded onto said proximal end of said guide wire and includes an interface washer adapted to engage a proximal bone segment; wherein said radially expandable anchor portion comprises at least two evenly spaced ribs formed between a plurality of longitudinal slots disposed through said sidewall and is disposed toward said distal end; wherein said radially expandable anchor portion is adapted to collapse upon relaxation of compression forces between distal and proximal segments of said tube or application of tension between distal and proximal segments of said tube; further comprising a second radially expandable anchor portion 4b; further comprising at least one semi-annular cut (at 36) in said tube 4.

Claims 1-3, 7, 8, 10-12, 16-18 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Laub (US 4,808,163). Laub teaches a device capable of positioning bone segments comprising: a flexible guide wire 26 having a proximal end

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and a distal end; a distal stop 22 disposed on said guide wire 26 about adjacent to said guide wire distal end; a proximal stop 31 disposed on said guide wire 26 about adjacent to said guide wire proximal end; and a flexible tube 11 disposable over said guide wire 26 and having a sidewall including a radially expandable anchor portion 16 adapted for radial expansion upon compression of said tube 11 between said distal stop 22 and said proximal stop 31; wherein said anchor portion 16 is disposed toward said distal end and comprises a plurality of evenly spaced ribs 18 formed between a plurality of longitudinal slots 17 disposed through said sidewall; wherein said radially expandable anchor 16 portion is adapted to collapse upon relaxation of compression forces between distal and proximal segments of said tube and adapted to collapse upon application of tension between distal and proximal segments of said tube 11; further comprising at least one semi-annular cut 14 in said tube 11.

Concerning the language of claim 2 "a dilator having a tapered distal surface, an at least partially transverse proximal surface and a tubular inner surface defining a longitudinal through hole; said dilator being disposable on said guide wire wherein said guide wire extends through said through hole and wherein said at least partially transverse proximal surface serves as said distal stop," it is noted that Laub discloses the use of a hollow needle to introduce guidewire 26 into vein 36. It is the examiner's position that this needle would inherently include all of the structural features of the dilator of claim 2. Because any needle has a transverse dimension at its proximal end which would appear as an annulus when viewed from the proximal end, it is believed the needle mentioned by Laub would thereby have "an at least partially transverse

proximal surface." Further, it is believed that the longitudinal through hole provides for the "countersunk" recitation of claim 3.

Claim Rejections - 35 USC § 103

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Davies as applied to claim 1 above and further in view of Culbert et al. (U.S. 6,648,890). Davies teaches all of the limitations of the present invention except the device comprising a bioactive material.

Culbert et al. teaches a related device for fixing together two bone segments which, as mentioned in lines 33-43 of column 10, "may contain one or more bioactive substances, such as antibiotics, chemotherapeutic substances, angiogenic growth factors, substances for accelerating the healing of the wound, growth hormones, antithrombogenic agents, bone growth accelerators or agents, and the like. Such bioactive implants may be desirable because they contribute to the healing of the injury in addition to providing mechanical support."

It would have been obvious to one having ordinary skill in the art at the time of the present invention to incorporate bioactive substances as taught by Culbert et al. into one or more parts or portions of the device taught by Davies so as to improve the healing of injury.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Davies as applied to claim 11 above and further in view of Culbert et al. (U.S. 6,648,890).

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Davies teaches all of the limitations of the present invention except the ribs of said anchor portion include a textured surface.

Culbert et al. teaches a related device for fixing together two bone segments in which, as mentioned in lines 46-48 of column 10, "osteoincorporation may be enhanced by providing a micropitted or otherwise textured surface on the anchor components."

It would have been obvious to one having ordinary skill in the art at the time of the present invention to form a textured surface as taught by Culbert et al. on the ribs of the device of Davies to enhance osteoincorporation.

Allowable Subject Matter

Claims 13-15 have been objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 4-6 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claim 23 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael B. Priddy whose telephone number is 571-272-2243. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael B. Priddy

Michael B. Priddy
May 7, 2007

EDUARDO O. ROBERT

NON-PATENT ADVISORY PATENT EXAMINER